Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) 1, 3-9, 12-18 and 19 are pending and under consideration.
2. Claim(s) 2, 10 and 11 have been cancelled.

Claim 1 has been amended, and now requires that the distal end of the at least one stent provides a distal, outflow end of the stent graft. Support for this limitation can be found throughout the specification and figures.

Claim 1 also now requires that the stent graft be placeable at the vascular treatment site such that the proximal end of the at least one stent is located upstream of the distal end of the at least one stent. The specification provides clear support for this limitation. In paragraph [0018], for example, it is stated that the proximal end of the stent graft is the end "at which the sleeve is folded over." By having the proximal end of the stent graft located upstream of the distal end, the folded material "will prevent blood flow between the layers" as described.

Claim 3 has been amended. It now requires that the distal stent frame end provides a distal, outflow end of the stent graft, and that the stent graft be placeable at the vascular treatment site such that the proximal stent frame end is located upstream of the distal stent frame end. Support for this limitation can be found throughout the specification as generally described above with regard to claim 1.

Claim 19 is new and patentable. Support for this claim can be found throughout the specification including at paragraphs [0023] and [0024]. Applicants believe that allowing claim 19 to remain in the application would not place a serious burden on the examiner.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 3-7 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas U.S. Patent No. 6,090,128 in view of Gregory U.S. Patent No. 5,990,379.

To establish a *prima facie* case of obviousness, the prior art references when combined must teach or suggest all of the claim limitations. The Douglas and Gregory references, when combined, fail to teach or suggest all of the claim limitations for any of claims 1, 3-7 and 12-16 as currently amended, and therefore a *prima facie* case of obviousness does not exist.

As amended, claim 1 requires that the distal end of the at least one stent provides a distal, outflow end of the stent graft, and that the first portion and the second portion of the sleeve be secured to at least the distal end of the at least one stent.

In the Douglas device, it is clear that the distal, outflow end of the device—the end through which blood flow exits the device—does not occur at the distal end of first stent **42** but instead occurs at the distal ends of second and third stents **48** and **50**. Thus, in order to meet claim 1 as amended, the Douglas reference (either as separately modified or when combined with the Gregory reference) would have to teach or suggest securing the tubular member **32** to the distal ends of second and third stents **48** and **50** which it clearly does not. In fact, such a modification is one from which the Douglas reference squarely teaches away. Modifying the Douglas device to have the tubular member **32** extend to the distal ends of the first and second limb members **34** and **36** would render the bifurcated Douglas device inoperable for its intended purpose since there needs to be separation between the two limbs in order for the device to be properly implanted, for example, as shown in FIG. 7G.

Claim 1 requires that the sleeve be secured at the distal end of the at least one stent, which provides the outflow end of the stent graft. It is notable that neither the Gregory reference nor the Douglas reference teaches or suggests securing the outer covering material at the distal, outflow end of the device. In these prior art devices, the covering material is always secured to the frame in a central region of the device (i.e., in an area spaced from the distal, outflow end). This distinction is important, because there are advantages to requiring that the covering material be secured (e.g., sutured) to the distal, outflow end. For example, in instances where the sleeve is secured to the frame with sutures, it may be beneficial to eliminate this additional foreign body material (i.e., the suture material) from non-distal regions of the device, for example, to eliminate it from central regions of the device (e.g., as required by the Gregory and Douglas references). As discussed in paragraphs [0015] and [0016] of the specification, for example, sleeves formed with remodelable ECM materials provide a framework for cells that after emplacement within a patient become remodeled by host tissue over time. Such materials are resistant to infection and do not cause an adverse immunological reaction. Thus, where a device according to claim 1 is

placed at a vascular treatment site, there is no requirement for centrally-located sutures and thus there is an opportunity for the ECM covering material to remodel in an uninterrupted manner along substantially the entire length of the stent graft. By unnecessarily introducing a suture or other foreign body into this longitudinal region of remodeling, it increases the chance that there will be an adverse immunological reaction in this region, and that the graft as a whole will be unsuccessful.

Claims 7-9, being dependent upon claim 1, are patentable for at least the reasons stated above.

Turning now to claim 3, currently amended claim 3 requires that there be a plurality of stents connected together to form a stent frame with lumens of the respective stents coaligned to form a common continuous lumen extending from a distal stent frame end to a proximal stent frame end, and that the distal stent frame end provides a distal, outflow end of the stent graft through which blood flowing through the stent graft can exit the stent graft.

As stated above with respect to claim 1, it is clear that the distal, outflow end of the Douglas device—the end through which blood flow exits the device—does not occur at the distal end of first stent **42** but instead occurs at the distal ends of second and third stents **48** and **50**. Thus, in order to meet claim 3 as amended, the Douglas reference (either as separately modified or when combined with the Gregory reference) would have to teach or suggest having a plurality of stents connected together to form a stent frame with lumens of the respective stents coaligned to form a common continuous lumen extending from a distal stent frame end (i.e., the distal, outflow end of the device) to a proximal stent frame end. The Douglas reference clearly does not teach or suggest this limitation, and in fact, such a modification is one from which the Douglas reference squarely teaches away. Modifying the Douglas device to have a plurality of stents with lumens of the respective stents coaligned to form a common continuous lumen extending from a proximal stent frame end to the distal, outflow end of the device would make the Douglas device a non-bifurcated device, and thus render it inoperable for its intended purpose.

Claims 4-6, being dependent upon claim 3, are patentable for at least the reasons stated above.

Turning now to claim 12, this claim requires that the stent frame define only a single lumen extending from a first end of the stent graft device to a second end of the stent graft device, and that the stent frame be provided by a single stent or by a plurality of stents connected together with lumens of the respective stents coaligned to form a common continuous lumen. An

additional requirement of claim 12 is that the first portion and the second portion of the sleeve be secured to at least the distal end of the stent frame.

For at least the reasons stated above, none of the cited references, as separately modified or when combined, teach or suggest all of the claim limitations for claim 12, and therefore a *prima facie* case of obviousness does not exist.

Claims 13-16, being dependent upon claim 12, are patentable for at least the reasons stated above.

Claims 8, 9, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas '128 in view of Gregory '379 and further in view of Buirge et al. U.S. Patent No. 5,693,085.

Buirge et al. do not fill the voids in teaching discussed above with respect to the Douglas and Gregory references. In fact, Buirge et al., like Gregory, uses a central suture line to join the sleeve.

For at least the reasons stated above, none of the cited references, as separately modified or when combined, teach or suggest all of the claim limitations for any of claims 8, 9, 17 and 18 as currently amended, and therefore a *prima facie* case of obviousness does not exist.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

By _____

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